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EXAMINER	
OU, JING RUI	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
05/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,007	MIALHE, CLAUDE	
	Examiner	Art Unit	
	JING RUI OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-10 and 12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-10 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment filed on 02/28/2011. Claims 1, 4-10, and 12-17 are pending. Claims 1 and 17 are independent. Claims 2, 3, and 11 are cancelled.

Claim Objections

2. Claims 1 and 4-17 are objected to because of the following informalities:

a) In the last paragraph of claim 1, the phrase "the distal end is able" should be corrected to "the distal end of the plunger is able."

b) In the fourth paragraph of claim 17, the limitation "front end" should be corrected to "a front end."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 1, 4-10, and 12-17 fails the 3-prong analysis set forth in the MPEP 2181 and will not be treated under 35 USC 112 sixth paragraph since the recitations "means for opening the nose" in claims 1 and 10 and "means for translation" in claims 1 and 17 are modified by sufficient structures for achieving the specified function.

4. Claim 13 is being treated under 35 USC 112 sixth paragraph, in which the "means of adjusting" requires a grip as supported by applicant's specification (Para. [0087]).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 4-10, 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In line 5 of the fourth paragraph of claim 1, the limitation "the auto-expandable element" is being unclear as to refer to which of the first and second auto-expandable element.

b) In the seventh paragraph of claim 1, the recitation "at the end furthest from the intermediate section" is being unclear at the end of what component and the intermediate section of what component..

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 4-10, and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al (US Pat. No.: 5,433,723) in view of Garza et al (US Pat. No.: 4,665,918) and Martinez et al (US Pat. No.: 5,593,412).

In regard to Claims 1, 4-10, and 12-17, Lindenberg et al discloses an implant delivery system, comprising: a vessel dilation device (Fig. 1) with an outer envelope (2); an implant (1), the implant includes an auto-expandable element (the distal end of the endoprosthesis 1, Col. 4, lines 25-29) which presses against the internal wall of the outer envelope (Fig. 1); the implant includes a second, hollow expandable element (the proximal end of the endoprosthesis 1) and a hollow intermediate section (the intermediate section of the endoprosthesis 1 is deformable by twisting since it is an expandable and bendable stent); wherein the first auto-expandable element is positioned in the outer envelop at a location closer to the nose in the distal direction than the second auto-expandable element (Fig. 1); a grip (5) that is an integral part of the outer envelope; a removable spacer (9), a plunger (part of 3 without tongues 4), a grip (12) that is an integral part of the plunger, and a central channel (Fig. 1) along the line of the outer envelope.

Lindenberg et al does not appear to disclose an inner sheath slidably disposed inside the outer envelop and outside the plunger, a grip that is an integral part of the inner sheath, and that the outer envelope has a tapered end piece and detailed structures of the end piece.

However, Garza et al teaches a stent delivery system comprising: an outer sheath 78) connected to a grip (86), an inner sheath (50) connected to a grip (64) and

slidably disposed inside the outer sheath, a plunger (the portion 18 defined from 22 to 26) connected to a grip (30) and slidably disposed inside the inner sheath and a spacer between each grip (Figs. 1-13b). Furthermore, Martinez et al teaches an implant delivery system, comprising of an outer envelope (sheath, 18, Fig. 1) having a tapered end piece (distal end portion 32 is tapered, Fig. 1) at the distal end of the outer envelope and an implant have expandable portion (stent, Fig. 10) that is pressed against the sheath and is in contact with the internal wall of a nose, whereby the end piece consists of the nose (the tapered distal end portion 32 is nose, Fig. 1) and means for opening the nose, consisting of at least two longitudinal slots (weakened areas, 41-45, Fig. 2A) which divide the nose into several segments (sections, 51-55, Fig. 2A), nose segments are joined as required along the slots when the nose is closed (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); temporary connector by slots between segments (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); and the nose includes a central residual passage (central opening, 50, Fig. 2A).

Lindenberg et al, Garza et al, and Martinez et al are analogous art because they are from the same field of endeavor, implant delivery system.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Lindenberg et al, Garza et al, and Martinez et al before him or her, to modify sheath and plunger of the implant delivery system of Lindenberg et al to include an inner sheath connected to a grip and slidably disposed inside the outer sheath, that plunger to be connected to a grip and slidably disposed inside the inner

sheath, and a spacer between each grip as taught by Garza et al and to modify the distal end of the outer envelope of Lindenberg et al to include a tapered end nose piece and detailed structures of the end nose piece as taught by Martinez et al.

The suggestion/motivation for modifying the sheath and plunger of the implant delivery system of Lindenberg et al to include an inner sheath connected to a grip and slidably disposed inside the outer sheath, that plunger to be connected to a grip and slidably disposed inside the inner sheath, and a spacer between each grip as taught by Garza et al would have been to provide an more convenient way of independently withdrawing each of the outer and inner sheaths and to permit selected distances to be maintained between each grip in the present of the spacers. The suggestion/motivation for modifying the distal end of the outer envelope of Lindenberg et al to include a tapered end nose piece and detailed structures of the end nose piece as taught by Martinez et al would have been to protect the implant from premature deployment and control the deployment of the implant. Until the delivery device reaches a target site, the distal end portion of the sheath is softened by exposing to a warm, physiologically compatible liquid and opened by the pushing force of the implant and the introducer, thereby to allow for retraction of the sheath and deployment of the implant (Martinez et al, Col. 3, lines 24-42). Applicant should have noted that the tapered end nose piece with slits is old and well-known in the art. For examples, both Johnson et al (US Pat No.: 6,596,011) and Fischell et al (US Pat. No.: 5,634,928) discloses an implant delivery device comprising a sheath having a taper end nose piece with slits. Furthermore, it is old and well-known that the nose includes a shape memory, which would facilitate the

withdrawn of the delivery system from body or enable insertion of another implant without withdrawing the sheath out of the body. In addition, duplication of the essential working parts of a device such as the grips and the spacer involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co., 193 USPQ 8*

Therefore, it would have been obvious to combine Garza et al and Martinez et al with Lindenberg et al to obtain the invention as specified in the instant claims.

Response to Arguments

10. Applicant's arguments filed 02/28/2011 have been fully considered but they are not persuasive.

The allegation on pages 12 and 21 of the remarks that Lindenberg does not teaches an endoprosthesis having a twistable section between two expandable sections is incorrect. The stent (1) in Lindenberg clearly has an intermediate twistable section between the end expandable sections since the whole stent can be deformed by twisting.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "only the auto-expandable element (24) will be in contact with the internal wall of the nose (14) in page 14 of the remarks) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The allegation on pages 14-16of the remarks that none of the cited documents suggests "a portion of an implant maintained by an internal wall of the inner sheath and another portion maintained by the internal wall of the outer envelope" and "an inner sheath being slidable within an outer envelope and able to push the rear end of the implant towards the distal end of the outer envelop to release the implant" is incorrect. Garza clearly discloses or teaches that both the outer envelope (78) and the inner sheath (50) maintain at least a portion of the implant as claimed. Applicant should be noted that the term "comprising" does not exclude either the inner sheath or the outer envelope from maintaining other portions of the implant. In addition, the inner sheath is capable to push the rear end of the implant towards the distal end of the outer envelop to release the implant in a certain degree by friction or by other mechanical means. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The combination of Lindenberg and Garza would suggest a sheath capable of release the implant outside of the outer sheath by retracting the outer envelope and pushing of plunger and pushing of the inner sheath by friction against the movement of the outer envelope.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the intermediate section which is not expandable does not press against the inner wall of the outer envelop" in page 18) are not recited in the rejected claim(s). Although

the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The allegation on page 19 of the remarks that the endoprosthesis of Lindenberg has not sufficient rigidity to open the nose mechanically is incorrect. The combination of the withdrawal of the outer envelope and the compression of the endoprosthesis would be capable to open the nose mechanically with the help of a softening liquid as taught by Garza.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the inner sheath which is able to rotate along the longitudinal axis of the device" and "the rotation of the applicator and the elements of the device" in page 20 of the remarks) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the plunger aims first at preventing the withdrawal of the implant when the sleeve (2) is moved back and then at pushing out the implant in order to finalize its delivery" in pages 21 and 22 of the remarks) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are

not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, Lindenberg clearly discloses that the implant is not moved by the withdrawal of the device (Fig. 5)

The outer envelope 2 of Lindenberg and sheath 18 of Martinez are capable to be used to constrain a self-expandable element. The combination of Linderberg and Martinez is to modify the outer envelop of Linderberg to include the nose feature of Martinez for protecting the implant from premature deployment and control the deployment of the implant.

Again, Garza clearly discloses or teaches that both the outer envelope (78) and the inner sheath (50) maintain at least a portion of the implant as claimed. Applicant should be noted that the term "comprising" does not exclude either the inner sheath or the outer envelope from maintaining other portions of the implant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING RUI OU whose telephone number is (571)270-5036. The examiner can normally be reached on 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, UYEN (JACKIE) HO can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. O./
Examiner, Art Unit 3773
05/05/2011

/Darwin P. Erezo/
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